4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA-2016-D-2343]

Hazard Analysis and Risk-Based Preventive Controls for Human Food; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of a revised draft Introduction, and a revised draft Appendix 1, within a multichapter guidance for industry entitled "Hazard Analysis and Risk-Based Preventive Controls for Human Food." This multichapter draft guidance, when finalized, will explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under our rule entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food." We revised the draft Introduction and draft Appendix 1: Known or Reasonably Foreseeable Hazards ("Potential Hazards") to address comments submitted on drafts that we made available in 2016. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-2343 for "Hazard Analysis and Risk-Based Preventive Controls for Human Food." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Food Safety (HFS-300), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that

office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Linda Kahl, Center for Food Safety and Applied Nutrition (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2784.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a revised draft Introduction and a revised draft Appendix 1 of a multichapter draft guidance for industry entitled "Hazard Analysis and Risk-Based Preventive Controls for Human Food." We previously announced the availability of several chapters of that draft guidance as shown in table 1.

Table 1.--Available Draft Chapters in Hazard Analysis and Risk-Based Preventive Controls for Human Food

Chapter No.	Chapter Title	Publication
N/A	Introduction	81 FR 57816, August 24, 2016
1	The Food Safety Plan	81 FR 57816, August 24, 2016
2	Conducting a Hazard Analysis	81 FR 57816, August 24, 2016
3	Potential Hazards Associated with the Manufacturing, Processing, Packing, and Holding of Human Food	81 FR 57816, August 24, 2016
4	Preventive Controls	81 FR 57816, August 24, 2016
5	Application of Preventive Controls and Preventive Control Management Components	81 FR 57816, August 24, 2016
6	Use of Heat Treatments as a Process Control	82 FR 41364, August 31, 2017
11	Food Allergen Program	88 FR 66457, September 27, 2023
14	Recall plan	84 FR 53347, October 7, 2019
15	Supply-Chain Program for Human Food Products	83 FR 3449, January 25, 2018
16	Acidified Foods	88 FR 66457, September 27, 2023
Appendix 1	Potential Hazards for Foods and Processes	81 FR 57816, August 24, 2016
Appendix 2	Food Safety Plan Forms	81 FR 57816, August 24, 2016
Appendix 3	Bacterial Pathogen Growth and Inactivation	81 FR 57816, August 24, 2016

We are issuing these revised sections of the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food." It does not establish any rights

for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. FSMA enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production.

Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), by adding section 418 (21 U.S.C. 350g) with requirements for hazard analysis and risk-based preventive controls for establishments that are required to register as food facilities under our regulations in 21 CFR part 1, subpart H, in accordance with section 415 of the FD&C Act (21 U.S.C. 350d). We have established regulations to implement these requirements within part 117 (21 CFR part 117).

The multichapter draft guidance for industry is intended to explain our current thinking on how to comply with the requirements for hazard analysis and risk-based preventive controls under part 117, principally in subparts C and G. One revised draft that we are announcing in this document is "Introduction and General Information Applicable to This Guidance." We revised the draft Introduction that we made available in 2016 to address comments submitted regarding the draft Introduction, include all draft definitions that we subsequently included in chapters we have made available, and add draft recommendations for training applicable to most topics covered in the multichapter guidance. We also added two administrative features. One feature is a comprehensive bibliography of references that we cited within the chapters previously made available, as well as references that we expect to cite in the additional chapters that we have included in the table of contents. Another feature is a compilation of resources that could be useful to persons who use the multichapter guidance.

The second revised draft that we are announcing in this document is "Appendix 1: Known or Reasonably Foreseeable Hazards ("Potential Hazards")." We revised the draft Appendix 1 that we made available in 2016 to add text providing context for what the Appendix is, how it was developed, and how it should be used. To address comments submitted regarding the draft Appendix, we made several changes, including: (1) significantly revised product categories (which emphasize ingredients that go into foods rather than finished foods that can be formulated with many variations of such ingredients); (2) replaced a series of tables listing known or reasonably foreseeable ("potential") process-related hazards with a discussion of such hazards; (3) provided a general discussion of food allergen hazards rather than identify known or reasonably foreseeable ("potential") food allergen hazards that could apply to multiple product categories; and (4) identified scientific, technical, or regulatory information that we considered when identifying some hazards that are known or reasonably foreseeable ("potential"), but less common, hazards in some food categories.

We intend to announce the availability for public comment of additional chapters of the draft guidance as we complete them. The titles of the additional chapters that we expect to make available for public comment are included in the table of contents for the complete multichapter guidance.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in part 117 have been approved under OMB control number 0910-0751.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/FoodGuidances, https://www.fda.gov/regulatory-information/search-fda-

guidance-documents, or https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Date: January 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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